LOW DOSE ASPIRIN- aspirin tablet, coated
Bryant Ranch Prepack

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

TCL 481R TABLETS

HOW SUPPLIED

Product: 71335-1382

NDC: 71335-1382-1 120 TABLET, COATED in a BOTTLE

NDC: 71335-1382-2 30 TABLET, COATED in a BOTTLE

NDC: 71335-1382-3 100 TABLET, COATED in a BOTTLE

NDC: 71335-1382-4 20 TABLET, COATED in a BOTTLE

NDC: 71335-1382-5 90 TABLET, COATED in a BOTTLE

NDC: 71335-1382-6 60 TABLET, COATED in a BOTTLE

NDC: 71335-1382-7 36 TABLET, COATED in a BOTTLE

Aspirin 81 mg EC Tablet

LOW DOSE ASPIRIN

aspirin tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71335-1382(NDC:49483-481)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	HEART
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71335-1382-4	20 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2015	
2	NDC:71335-1382-7	36 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2015	
3	NDC:71335-1382-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2015	
4	NDC:71335-1382-3	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2015	
5	NDC:71335-1382-5	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2015	
6	NDC:71335-1382-1	120 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2015	
7	NDC:71335-1382-2	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/19/2015	

Labeler - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-1382) , RELABEL(71335-1382)