

Proposed packaging material		
Code	PENTAB500-L-MY-01.01	
Size		
Submission	☐ NDA ☐ Renewal ☒ Variation change detail no.: CCDS 16	
Code of previous version	CSAT.0097	
Changes	Deficiency for CCDS16, requested by HA to update the inner label to have full product name on it	
	☐ CCDS version: ☐ Core PIL version:	☐ SPC country/version/date: ☐ LAC no.:
Name & Date	JIWO, 07-03-2019	

PENTASA® Prolonged Release Tablets 500mg Mesalazine Ferring										PENTASA® Prolonged Release Tablets 500mg Mesalazine Ferring									
Exp:	MM	YYYY			Exp:	MM	YYYY			Exp:	MM	YYYY			Exp:	MM	YYYY		
Mfg:	MM	YYYY			Mfg:	MM	YYYY			Mfg:	MM	YYYY			Mfg:	MM	YYYY		
Batch No.:	Y12345X				Batch No.:	Y12345X				Batch No.:	Y12345X				Batch No.:	Y12345X			
PENTASA® Prolonged Release Tablets 500mg Mesalazine Ferring										PENTASA® Prolonged Release Tablets 500mg Mesalazine Ferring									
Exp:	MM	YYYY			Exp:	MM	YYYY			Exp:	MM	YYYY			Exp:	MM	YYYY		
Mfg:	MM	YYYY			Mfg:	MM	YYYY			Mfg:	MM	YYYY			Mfg:	MM	YYYY		
Batch No.:	Y12345X				Batch No.:	Y12345X				Batch No.:	Y12345X				Batch No.:	Y12345X			

Date: 11-MAR-2019

Title

Mockup MOCKUP-PENTASA-TAB-500MG-MY

Item N°

NA

Proof N°

02

Variable Data

line 1:

Expiry Date

line 2:

Manufacturing Date

line 3:

Lot Number

line 4:

NA